

Attachment #6

EA-101 Instructions

6 March 2001

Procedure for transfer of a select agent

The purpose of the CDC EA-101 form is to provide a method for the documentation of the transfer of a select agent. An EA-101 form must be completed for each transfer of a select agent. A copy of each EA-101 must be kept by the responsible facility official (RFO) for five years.

Prior to transferring a select agent

Before a select agent is transferred, both the sender (transferor) and receiver (requestor) facilities must be registered with the CDC. The requestor fills out blocks 1 and 2 of the EA-101 form and submits it, with a copy of the requesting facility's registration certificate, to the transferor. The transferor's responsible facility official (RFO) must verify with the requestor's RFO, and if appropriate, with the CDC, that the requesting facility: (1) retains a valid, current registration for the select agent being requested; (2) the person requesting the select agent is an employee of the requesting facility; and, (3) that the proposed use of the agent by the requestor is correctly indicated on CDC Form EA-101. For biosecurity reasons, the select agent registration certificate does not have information regarding which specific select agent(s) a facility is registered for. If the transferor cannot verify the registration status of the requestor, there is suspicion that the agent may not be used for the requested purpose, or there are any other concerns, then the transferor should consult with the CDC.

Transfer:

(a) Shipment of the select agent to the requestor

The transferor should ship the material to the receiver only after the transferor has verified the information in blocks 1 and 2 of the EA-101. The transferor fills out Section 3 and the shipping information in Section 4, including the date the agent was shipped. Select agents must be packaged, labeled, and shipped in accordance with all federal regulations (e.g., 42 CFR 72, and 49 CFR 100-180) and international (IATA) regulations. It is highly recommended that the transferor utilize a method for tracking the movement of the select agents being shipped. Return receipt is required by law for some select agents listed in 42 CFR part 72¹.

(b) Receipt of the select agent by the requestor

The RFO from the receiver's facility must acknowledge receipt of the agent to the transferor by telephone or otherwise electronically within 36 hours of receipt. The receiver's RFO is also required to provide a paper copy or facsimile transmission of receipt to the transferor within three business days of receipt of the agent.

¹*Coccidioides immitis*; Ebola virus; *Francisella tularensis*; Viruses causing HPS; CCHF; Junin Virus; Machupo virus; Lassa virus; Marburg virus; *Burkholderia mallei*; *Burkholderia pseudomallei*; Tick-borne encephalitis virus complex; Variola major virus; *Yersinia pestis*

(c) Transmittal of the EA-101 form to the CDC

After telephonic acknowledgment of receipt of the agent, the transferor writes in the date the agent was received in Section 4 of the EA-101 form. The transferor is required to provide a completed paper copy or facsimile transmission of the EA-101 form within 24 hours to the CDC. In addition, we recommend that a completed copy of the CDC Form EA-101 be sent to the receiver as well at the same time. This not only provides the receiver with a courtesy copy of the completed form, but assists the receiver if and when they need to complete Section 5 in the future (below).

Destruction or depletion of a select agent

When a select agent from a transfer is depleted or destroyed, the RFO of the facility must complete Section 5 of the CDC Form. A copy or FAX of the EA-101 form must be sent to the CDC Select Agent Program, 1600 Clifton Road, NE., Mail Stop E-79, Atlanta, GA 30333. FAX: 404-498-2265.

Steps in transferring a select agent

Requestor RFO	Transferor RFO
1. Completes agent description (Block 1)	
2. Completes requestor information (Block 2)	
3. Faxes form EA-101 and registration certificate to transferor	
	4. Verifies registration information
	5. Completes transferor information
	6. Completes shipping information
	7. Oversees packaging and shipment of agent to requestor. Sends shipment.
8. Receives agent	
9. Requestor RFO notifies transferor RFO of receipt of agent via facsimile or telephone within 36 hours (or provides paper copy to the transferor RFO within 3 days)	
	10. Transferor enters date agent received in block 4
	11. Transferor faxes completed form EA-101 to CDC within 24 hours
12. Retains paper record for 5 yr, or retains record 5 yr after agent consumed or destroyed, whichever is longer	12. Retains paper record for 5 yr, or retains record 5 yr after agent consumed or destroyed, whichever is longer